AUTHORITY: Secs. 1102, 1871, 1894(f), and 1934(f) of the Social Security Act (42 U.S.C. 1302, 1395, 1395eee(f), and 1396u–4(f)).

SOURCE: 64 FR 66279, Nov. 24, 1999, unless otherwise noted.

EDITORIAL NOTE: Nomenclature changes to part 460 appear at 67 FR 61504, Oct. 1, 2002.

Subpart A—Basis, Scope, and Definitions

§ 460.2 Basis.

This part implements sections 1894, 1905(a), and 1934 of the Act, which authorize the following:

(a) Medicare payments to, and coverage of benefits under, PACE.

(b) The establishment of PACE as a State option under Medicaid to provide for Medicaid payments to, and coverage of benefits under, PACE.

§ 460.4 Scope and purpose.

(a) *General.* This part sets forth the following:

(1) The requirements that an entity must meet to be approved as a PACE organization that operates a PACE program under Medicare and Medicaid.

(2) How individuals may qualify to enroll in a PACE program.

(3) How Medicare and Medicaid payments will be made for PACE services.

(4) Provisions for Federal and State monitoring of PACE programs.

(5) Procedures for sanctions and terminations.

(b) *Program purpose.* PACE provides pre-paid, capitated, comprehensive health care services designed to meet the following objectives:

(1) Enhance the quality of life and autonomy for frail, older adults.

(2) Maximize dignity of, and respect for, older adults.

(3) Enable frail, older adults to live in the community as long as medically and socially feasible.

(4) Preserve and support the older adult's family unit.

§ 460.6 Definitions.

As used in this part, unless the context indicates otherwise, the following definitions apply:

Contract year means the term of a PACE program agreement, which is a calendar year, except that a PACE organization's initial contract year may be from 12 to 23 months, as determined by CMS.

Medicare beneficiary means an individual who is entitled to Medicare Part A benefits or enrolled under Medicare Part B, or both.

Medicaid participant means an individual determined eligible for Medicaid who is enrolled in a PACE program.

Medicare participant means a Medicare beneficiary who is enrolled in a PACE program.

PACE stands for programs of all-inclusive care for the elderly.

PACE center is a facility which includes a primary care clinic, and areas for therapeutic recreation, restorative therapies, socialization, personal care, and dining, and which serves as the focal point for coordination and provision of most PACE services.

PACE organization means an entity that has in effect a PACE program agreement to operate a PACE program under this part.

PACE program means a program of all-inclusive care for the elderly that is

operated by an approved PACE organization and that provides comprehensive healthcare services to PACE enrollees in accordance with a PACE program agreement.

PACE program agreement means an agreement between a PACE organization, CMS, and the State administering agency for the operation of a PACE program.

Participant means an individual who is enrolled in a PACE program.

Services includes both items and services.

State administering agency means the State agency responsible for administering the PACE program agreement.

Trial period means the first 3 contract years in which a PACE organization operates under a PACE program agreement, including any contract year during which the entity operated under a PACE demonstration waiver program.

[64 FR 66279, Nov. 24, 1999, as amended at 71 FR 71334, Dec. 8, 2006]

Subpart B—PACE Organization Application and Waiver Process

§ 460.10 Purpose.

This subpart sets forth the application requirements for an entity that seeks approval from CMS as a PACE organization and the process by which a PACE organization may request waiver of certain regulatory requirements. The purpose of the waivers is to provide for reasonable flexibility in adapting the PACE model to the needs of particular organizations (such as those in rural areas).

[67 FR 61504, Oct. 1, 2002]

§ 460.12 Application requirements.

(a) *General.* (1) An individual authorized to act for the entity must submit to CMS a complete application that describes how the entity meets all requirements in this part.

(2) CMS accepts applications from entities that seek approval as PACE organizations beginning on February 22, 2000 except for the following:

(i) Beginning on November 24, 1999, CMS accepts applications from entities that meet the requirements for priority consideration in processing of applications.

(ii) Beginning on January 10, 2000, CMS accepts applications from entities that meet the requirements for special consideration in processing applications.

(b) *State assurance.* An entity's application must be accompanied by an assurance from the State administering agency of the State in which the program is located indicating that the State—

(1) Considers the entity to be qualified to be a PACE organization; and

(2) Is willing to enter into a PACE program agreement with the entity.

[64 FR 66279, Nov. 24, 1999, as amended at 67 FR 61505, Oct. 1, 2002; 71 FR 71334, Dec. 8, 2006]

§ 460.14 [Reserved]

§ 460.16 [Reserved]

§ 460.18 CMS evaluation of applications.

CMS evaluates an application for approval as a PACE organization on the basis of the following information:

(a) Information contained in the application.

(b) Information obtained through onsite visits conducted by CMS or the State administering agency.

(c) Information obtained by the State administering agency.

§ 460.20 Notice of CMS determination.

(a) *Time limit for notification of determination.* Within 90 days after an entity submits a complete application to CMS, CMS takes one of the following actions:

(1) Approves the application.

(2) Denies the application and notifies the entity in writing of the basis for the denial and the process for requesting reconsideration of the denial.

(3) Requests additional information needed to make a final determination.

(b) *Additional information requested.* If CMS requests from an entity additional information needed to make a final determination, within 90 days after CMS receives all requested information from the entity, CMS takes one of the following actions:

(1) Approves the application.

(2) Denies the application and notifies the entity in writing of the basis